

**c.) Remarks****Interview Summary**

Applicants would like to thank the examiner for granting the telephone interview of Thursday, March 9, 2006. In that interview, the applicants proposed the amendments entered herein. Agreement was reached with respect to the outstanding rejections under § 102. However, the examiner stated that the amendments under § 103(a) were not overcome. In this request for RCE, applicants formally amend the claims according to the proposed amendments and additionally amend the claims to recite “articulating” surfaces (instead of “cooperating” surfaces). Applicants also provide arguments for patentability with respect to all of the outstanding rejections.

**Request for Continued Examination, Amendment and Response**

As of this RCE, amendment and response, claims 7-15 remain pending; claims 1-6 are canceled herein. Support for the amendments to claims 7-10 and 12-13 is found in the specification, among other places, at paragraphs [0048], [0049], [0056], [0060], and [0064].

**Outstanding Rejections/Objections**

The Examiner has entered the following rejections:

1. Claims 1-2 are rejected under 35 USC § 102(b), as being anticipated by U.S. Patent 4,281,420 to Raab (“Raab `420”).
2. Claims 7-8, 11, and 14-15 are rejected under 35 USC § 102(e) as being anticipated by U.S. Patent 6,290,726 to Pope et. al. (“Pope `726”).
3. Claims 1-7 and 11-13 are rejected under 35 USC § 103(a) as being unpatentable over U.S. Patent 5,674,293 to Armini et. al. (“Armini `293”) in view of Raab `420.

4. Claims 9-10 are rejected under 35 USC § 103(a) as being unpatentable over Armini '293.

Applicants address each rejection in turn.

1. Rejection of Claims 1-2 under 35 USC § 102(b)

The examiner has rejected claims 1-2 under 35 USC § 102(b), as being anticipated by Raab '420.

The amendments made herein obviate this rejection. Because the relevant claims under this rejection have been canceled, this rejection is no longer at issue. Accordingly, applicants respectfully request that the examiner withdraw this rejection.

2. Rejection of Claims 7-8, 11, and 14-15 under 35 USC § 102(e)

The examiner has rejected claims 7-8, 11, and 14-15 under 35 § 102(e) as being anticipated by Pope '726. Applicants respectfully assert that this rejection is overcome by the amendments made herein.

The invention of Pope '726 is a diamond-on-diamond bearing surface. Nowhere does Pope '726 teach or disclose a prosthesis having at least one surface of diffusion-bonded blue-black or black oxidized zirconium. As discussed at length in the specification, the blue-black or black oxidized zirconium surface of the instant claims is a specific oxide composition that is distinct from passive oxides that form spontaneously in the presence of oxygen. It is formed only under certain conditions. The blue-black or black oxidized zirconium of the instant claims is discussed in the instant specification, *inter alia*, at paragraphs [0056] to [0059]. The composition is characterized by an oxide zone and a diffusion hardened zone below this. At paragraph [0056], the specification teaches:

The base (i.e., substrate) zirconium containing metal alloys are cast or machined by conventional methods to the shape and size desired to obtain a prosthesis substrate. The substrate is then subjected to process conditions which cause the natural (in situ) formation of a tightly adhered, diffusion-bonded coating of oxidized zirconium on its surface. The process conditions include, for instance, air, steam, or water oxidation or oxidation in a salt bath. These processes ideally provide a thin, hard, dense, blue-black or black, low-friction wear-resistant oxidized zirconium film or coating of thickness typically on the order of several microns ( $10^{-6}$  meters) on the surface of the prosthesis substrate. Below this coating, diffused oxygen from the oxidation process increases the hardness and strength of the underlying substrate metal.

In order to make clear in the claims that the invention is limited by the presence of this specific oxide, the present amendments include the insertion of the modifier “diffusion-bonded” before the recitation of “blue-black or black oxidized zirconium.”

In the examiner’s “Response to Arguments” in the office action of February 24, 2006, the examiner notes that “the law of anticipation does not require that the reference “teach” what the subject patent teaches, but rather that the claims under attack “read on” something in the reference. This statement does not address the fact that nothing in Pope ‘726 “reads on” the claims under attack because the prosthesis claims under attack are limited by a surface of diffusion-bonded blue-black or black oxidized zirconium. Applicants note that this limitation is not a recitation of intended use, but rather a limitation on the device itself – it only reads on a prosthesis having a surface of diffusion-bonded blue-black or black oxidized zirconium (i.e., it does not read on prosthesis lacking a surface of diffusion-bonded blue-black or black oxidized zirconium). Of course, the pending device claims are further limited by the requirement that the surface of diffusion-bonded blue-black or black oxidized zirconium articulate against a surface of cross-linked polyethylene. These limitations speak to what the device is (i.e., they are structural and compositional limitations); they are not limitations relating to how the device is intended to be used. The device is simply intended to be used as a vertebral disc prosthesis.

Nowhere does Pope `726 teach or disclose a prosthesis having at least one surface of diffusion-bonded blue-black or black oxidized zirconium. Additionally, nowhere does Pope `726 teach or disclose a prosthesis having at least one surface of diffusion-bonded blue-black or black oxidized zirconium articulating against least one surface of cross-linked polyethylene. With regard to cross-linked polyethylene, Pope `726 fairly teaches away from the use of cross-linked polyethylene. At the portion of the specification cited by the examiner (col. 4, ll. 42-53), Pope `726 teaches that cross-linking of polyethylene has “unanticipated effects” (col. 4, ll. 44) and has “deleterious effects” (col. 4, ll. 50). Pope `726 criticizes the use of cross-linked polyethylene and teaches that a diamond-on-diamond bearing surface is superior. Pope `726 is fairly interpreted by one of ordinary skill in the art as teaching away from the use of cross-linking for prosthetic implants wherein the cross-linked polyethylene articulates against diamond or other surface of high hardness.

Thus, the teachings of Pope `726 contrast sharply with the invention of the instant claims. In the instant invention, the inventors teach minimizing any potential problems with cross-linked polyethylene by articulating against a surface of diffusion-bonded blue-black or black oxidized zirconium (or other abrasion-resistant surface). Pope `726, on the other hand, suggests elimination of cross-linked polyethylene altogether (for articulation against diamond and other hard surfaces).

Thus, Pope `726 fails to teach or suggest a prosthesis with at least one surface of diffusion-bonded blue-black or black oxidized zirconium and therefore fails to provide a device which “reads on” the rejected claims. Additionally, Pope `726 fairly teaches away from the use of cross-linked polyethylene for articulating surfaces of prosthetic devices wherein the other articulating surface is diamond or other surface with high hardness. In light of the arguments

provided herein and the corresponding amendments, applicants respectfully request that the examiner withdraw the rejection of claims 7-8, 11, and 14-15 under 35 USC § 102(e) over Pope '726.

3. Rejection of Claims 1-7, and 11-13 under 35 USC § 103(a)

The examiner has rejected claims 1-7, and 11-13 under 35 § 103(a) as being unpatentable over Armini '293 in view of Raab '420. The examiner asserts that Armini '293 discloses all elements of the instant claims except that of the at least one surface of cross-linked polyethylene. The examiner then asserts that one of ordinary skill in the art would use the teachings of Raab '420 to supply the teaching of at least one surface of cross-linked polyethylene. Applicants believe the present claim amendments overcome this rejection.

As claims 1-6 have been canceled, the comments below apply to claims 7-15, as amended herein.

Raab '420 is not concerned with articulating surfaces, and does not teach a prosthesis having a vertebral disc prosthesis having a surface of diffusion-bonded blue-black or black oxidized zirconium articulating against cross-linked polyethylene. Raab '420 does mention UHMWPE at col. 3, line 14, and cross-linking of UHMWPE at col. 6, ll. 34-44. At col. 3, ll. 5-18, Raab '420 uses the term "bearing" in reference to "a polymer such as UHMWPE bearing a thin, high strength PMMA film." However, in addition to the fact that Raab '420 nowhere teaches a surface of diffusion-bonded blue-black or black oxidized zirconium "bearing" against cross-linked polyethylene, where Raab '420 does use the term "bearing", it clearly refers to non-articulating contact. Raab '420 is concerned only with the fixation surfaces of the prosthesis (non-articulating) surfaces only.

The term “bearing” in Raab `420 is used only to mean “contact” (i.e., “a polymer such as UHMWPE bearing a thin, high strength PMMA film”), it nowhere teaches or suggests the use of cross-linked polyethylene articulating against any other surface, let alone a surface of diffusion-bonded blue-black or black oxidized zirconium. An articulating surface in a prosthetic device is subject much greater loads, and therefore wear, than are non-articulating surfaces. The instant invention is based on the recognition that a diffusion-bonded blue-black or black oxidized zirconium articulating against cross-linked polyethylene provides a superior articulating interface in terms of wear resistance. Applicants are amending the claims to recite articulating surfaces in order to have this distinction expressly appear in the claims. Support for this amendment appears, for example, at paragraph [0064].

Nowhere does Armini `293 teach or disclose a vertebral prosthesis having a surface of diffusion-bonded blue-black or black oxidized zirconium articulating against cross-linked polyethylene. While Armini `293 discloses an articulating, ion-implanted, zirconium oxide (see, for example the abstract of Armini `293), it nowhere discusses the nature of the surface that its device articulates against. The corresponding surface in the instant claims is a diffusion-bonded blue-black or black oxidized zirconium, not an ion-implanted, zirconium oxide. Notwithstanding this difference, there is no teaching anywhere in Armini `293 of an ion-implanted zirconium oxide articulating against cross-linked polyethylene. In contrast, the inventors in the instant specification described the unexpected wear performance of surfaces of diffusion-bonded blue-black or black oxidized zirconium articulating against cross-linked polyethylene. Nowhere are such articulating interfaces taught or suggested by Armini `293.

In the examiner’s “Response to Arguments” in the office action of February 24, 2006, the examiner notes that “the law of anticipation does not require that the reference “teach” what the

subject patent teaches, but rather that the claims under attack “read on” something in the reference. The examiner made this statement in references to the applicants earlier comments regarding the Armini '293 reference. This statement does not address the fact that nothing in Armini '293 “reads on” the claims under attack because the prosthesis claims under attack are limited by a surface of diffusion-bonded blue-black or black oxidized zirconium articulating against cross-linked polyethylene. Applicants note that this limitation is not a recitation of intended use, but rather a limitation on the device itself – it only reads on a prosthesis having a surface of diffusion-bonded blue-black or black oxidized zirconium articulating against cross-linked polyethylene (i.e., it does not read on prosthesis lacking a surface of diffusion-bonded blue-black or black oxidized zirconium articulating against cross-linked polyethylene). This limitation speaks to what the device is (i.e., it is structural and compositional in nature); it is not a limitation relating to how the device is intended to be used. The device is simply intended to be used as a vertebral disc prosthesis.

Thus, the central limitation in the pending claims of a vertebral prosthesis having an articulating couple of diffusion-bonded blue-black or black oxidized zirconium and cross-linked polyethylene is lacking in both Raab '420 and Armini '293. Neither reference is concerned with cross-linked polyethylene as an articulating surface, let alone as an articulating surface against the diffusion-bonded blue-black or black oxidized zirconium of the instant invention. Neither of these references discloses a vertebral prosthesis which reads on the pending claims, and therefore, the combination of the two references similarly fails to disclose a vertebral prosthesis which reads on the pending claims. Accordingly, the combination of Armini '293 with Raab '420 would not teach or suggest, to one of ordinary skill in the art, a vertebral prosthesis having a diffusion-bonded blue-black or black oxidized zirconium articulating against cross-linked

polyethylene. Because of this deficiency in both Armini `293 and Raab `420, neither reference taken alone, nor their combination, renders the instant claims unpatentable under 35 USC § 103(a).

In light of the arguments provided, applicants respectfully request that the examiner withdraw this rejection under 35 USC § 103(a) over Armini `293 in view of Raab `420 as it applies to pending claims 7 and 11-13.

4. Rejection of Claims 9-10 under 35 USC § 103(a)

The examiner has rejected claims 9-10 under 35 § 103(a) as being unpatentable over Armini `293. The examiner asserts that Armini `293 discloses all elements of the instant claims except that of a surface of blue-black or black oxidized zirconium of between 1 and 20 microns. The examiner notes that “where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. Applicants respectfully assert that this rejection is overcome by the amendments made herein.

Applicants assert that the amendments and arguments provided by the applicants herein place the base independent claim (claim 7) in condition for allowance. Accordingly, claims 9 and 10, which merely limit the base claim in terms of the thickness of the diffusion-bonded blue-black or black oxidized zirconium, should also be allowable.

In light of the amendments and arguments provided, applicants respectfully request that the examiner withdraw the rejection of claims 9-10 under 35 USC § 103(a) over Armini `293.

**d.) Conclusions**

In light of the amendments and arguments made herein, Applicants respectfully assert that the pending claims are in condition for allowance. Because the Examiner's rejections have been addressed, Applicants respectfully request withdrawal of the outstanding rejections. Accordingly, Applicants earnestly request allowance of the application. This is intended to be a complete response. If any issues remain outstanding, please contact the undersigned for resolution of the same.

Applicants herein submit the fee for a Request for Continued Examination and believe that no other fees are due or associated with the filing of this document. However, if Applicants are in error, the Commissioner is hereby authorized to draw any additional fees associated with this filing from Deposit Account No. 06-2375, under Order No. P02228US1/10105654, from which the undersigned is authorized to draw.

Respectfully submitted,

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